

REMARKS

In the Office Action, Claim 15 was rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to meet the written description requirement. Claims 13 and 23 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claims 1, 2, 4-9, and 12 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 4,680,262 to Bochner et al. ("Bochner"). Claims 14 and 16-24 were objected to as depending from a rejected base claim, but were said to be allowable if rewritten in independent form.

Applicants appreciate the Examiner's indication that Claims 14 and 16-24 would be allowed if recast in independent form. To this end, Claim 13 is amended to incorporate the subject matter of Claim 14, which is in turn canceled without prejudice. And Claim 15 is amended to recite the specific agents that were recited in now canceled Claim 16. New claim 25 is added. No new matter is added into the case by these amendments, and they should reconfigure the claims consistent with the Examiner's indication of her view of the allowable subject matter in these claims. All objections and rejections are respectfully traversed. Reconsideration and favorable action are respectfully requested in light of the foregoing amendments and the following remarks.

A. Claim 15 Meets the Requirements of §112.

The Examiner asserts that the term "agent" in Claim 15 is indefinite. While the meaning of the term "agent" is believed to be a matter of simple common sense and readily known to a person of ordinary skill in the pharmaceutical arts from the specification and from the context of the claims themselves, Claim 15 has nonetheless been amended to include a Markush group of "agents" from Claim 16 for use in connection with bringing about an osmotic shock. Claim 16 is therefore canceled, without prejudice. Thus, the term "agent" called for in Claim 15 and said to be indefinite is now specifically defined in Claim 15 itself by way of a Markush containing an illustrative list group of one or more specific "agents" that can be used in the practice of the claimed process. Accordingly, it is believed that any alleged issue

with regard to the term “agent” in Claim 15 has been adequately addressed, and that the claim now unquestionably meets the requirements of 35 U.S.C. §112.

B. Claims 13 and 23 Are Not Indefinite.

Claim 13 is amended to incorporate the subject matter of Claim 14, the latter of which is hereby cancelled, as suggested in the Office Action. Hence, Applicants believe Claim 13 to be more than sufficiently definite. Claim 23, rejected as dependent from rejected Claim 13, is also no longer allegedly indefinite. Accordingly, reconsideration and allowance of Claims 13 and 23 are hereby respectfully requested.

C. Claims 1, 2, 4-9, and 12 are Not Anticipated by the Cited Reference.

Claims 1, 2, 4-9, and 12 were rejected as allegedly anticipated by Bochner. As will be shown, this rejection is not well taken.

Bochner is said to disclose the use of “osmotic shock” to extract interferon from a eukaryotic cell, using sucrose as the “shock” agent. With all due respect, this is not a correct interpretation of Bochner. Bochner never says that osmotic shock has been used to extract interferon of any type from any sort of cell. Bochner mentions in its background section at Col. 2, lines 45-57, that “osmotic shock” techniques have been attempted in the past for recovering periplasmic proteins, but then proceeds to criticize against use of osmotic shock as ineffective. Osmotic shock is said to be disadvantageous because it is believed to require treatment of “viable” cells with a high tonicity solution followed by a cold water wash of low tonicity to release the proteins. Bochner further denigrates osmotic shock and other techniques in the ensuing text, teaching it is better practice to kill cells by contacting them with lower alkanols, such as ethanol and 1-butanol, in the presence of heat. (Col. 4, line 56 – Col. 5, line 13).

There can be no doubt that Bochner teaches against the concepts that underlie Claim 1, and Bochner certainly does not disclose all of the steps of Claim 1. Bochner teaches persons of skill in the art not to use osmotic shock for recovering “periplasmic protein,” but without describing how osmotic shock was supposedly done previous to Bochner. Accordingly, a person of ordinary skill reading Bochner would be directed away from even trying to use osmotic shock to recover

material from cells of any type, much less doing so in a method like that claimed by Applicants for recovering interferon alpha 2. Disparaging the use of osmotic shock techniques on “viable” cells, Bochner discourages the skilled worker from attempting any method that would practice the steps of Claim 1 and, thus, Bochner cannot reasonably be said to disclose the subject matter of Claim 1, or any of Applicant’s other claims.

Not only is Bochner fundamentally oriented against using osmotic shock methods for treating cells in general, it also fails to disclose how one of skill would carry out a method for making and recovering protein according to Applicant’s claims. Bochner does not describe all the steps of claim 1 for making and recovering interferon alpha 2 from prokaryotic host cells in a fermentation medium according to Applicant’s claims, where cells that have been genetically modified to produce interferon alpha 2 and to then secret it into the cell periplasm are subjected to osmotic shock, applied directly to the fermentation medium itself, to enable recovery of interferon from the periplasm in a way that avoids release of other cell contents into the medium and associated complications, etc.

It is axiomatic that a reference cannot lawfully be said to anticipate a claim unless the reference is shown to (1) disclose each and every element and limitation of the claim within its “four corners” and (2) be enabling for the alleged anticipatory subject matter. It should now be patently obvious that Bochner does not anticipate Claim 1, or any claim dependent therefrom. Among other things, Bochner does not describe a process that ferments genetically transformed prokaryotic cells in a fermentation medium so as to cause secretion of interferon alpha 2 into the cells periplasm and then applies osmotic shock directly to the cells in the fermentation medium to extract interferon alpha 2 from the prokaryotic cell periplasm as called for in Claim 1 or the other rejected claims.

Even if Bochner did mention all the steps and requirements of Applicant’s claimed method, which it does not, Bochner still would not be enabling for all the steps in the claimed method. Bochner broadly discourages use of osmotic shock as an ineffective way to recover proteins from cells. Apart from criticisms of a generalized nature vis-a-vis an osmotic shock approach, Bochner fails to describe how one would actually practice steps of a method that uses osmotic shock. None of the steps of Applicant’s claimed method are disclosed in Bochner, and Bochner’s general

disdain of osmotic shock methods, without saying how they are / were done, can hardly be said to anticipate Applicant's claim, and it certainly would not enable the practice of such a claim.

Again, Bochner focuses on an entirely different method, which acts in a totally different manner from osmotic shock (by its own admission) and upon cells that have been formed into a paste and subjected to freezing and thawing cycles, etc. for recovery of HGH. The only detailed description in Bochner is of a method unlike that of osmotic shock, and one that would undoubtedly cause spillage of cell contents and other interior cell debris, etc. into the material from which the desired HGH is then said to be recovered. There is no disclosure at all of how to carry out the materially different technology claimed by Applicant, much less an "enabling" disclosure of how to do so.

Bochner's "nonspecific" derision of osmotic shock methods fails to anticipate Applicant's claim to a materially different methodology using, among other things, osmotic shock applied directly to cells in a fermentation medium for selective extraction of interferon alpha 2 from the cell's periplasm. Accordingly, Bochner does not anticipate Applicant's claimed method under 35 USC § 102. Reconsideration and allowance of Claims 1, 2, 4-9, and 12 are hereby respectfully requested.

D. The Objection to Claims 14 and 16-24.

Claims 14 and 16-24 were objected to as dependent upon a rejected base claim, but were said to otherwise be allowable. While Applicants have shown herein that the base claims from which these claims depend do in fact patentably distinguish over the cited art, they have nevertheless combined the subject matter of Claim 14 into Independent Claim 13. Applicants believe that Claim 13 is fully in compliance with Section 112, and should be allowable, as well as all the claims dependent thereupon. Accordingly, the objections to Claims 14 and 16-24 are hereby moot. Reconsideration and allowance of Claims 16-24 are hereby respectfully requested.

CONCLUSION

Applicants respectfully submit that the application is now in condition for allowance. Action in accordance therewith is respectfully requested.

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In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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